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| 10/550,439 | 09/22/2005 | Thomas J. Webster | 3220-100522 | 3174 |
| 23643 7590 03/04/2010 BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204 | | | | |
| EXAMINER | | | | |
| MAL, NGOC LAN THI | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary

Application No.

10/550,439

Applicant(s)

WEBSTER ET AL.

Examiner

NGOCLAN T. MAI

Art Unit

1793

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

claims 1-16 are under examination, wherein claims 1, 2, 4, 6, 7, 9, and 11 are amended and claims 12-16 are newly added.

Status of Previous Rejection

With respect to the amended feature of claims 1, 2, 4, 5, 7, 9 and 11, they do not change the scope of the claims. Therefore the rejections to claims 1-4, 8-11 under 35 U.S.C. 103(a) as being unpatentable over Yadav (U.S. Patent No. 6,572,672), claims 5-6 under 35 U.S.C. 103(a) as being unpatentable over Yadav (U.S. Patent No. 6,572,672) in view of Oshida (U.S. Patent No. 6,183,255) and claim 7 under 35 U.S.C. 103(a) as being unpatentable over Yadav (U.S. Patent No. 6,572,672) in view of Davison (U.S. Patent No. 5,415,704) in the previous office action dated May 14, 2009 are maintained and properly applied herein.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yadav et al. (U.S. Patent No. 6,572,672).

Regarding claim 13, Yadav discloses biomedical material used for forming biomedical orthopedic devices which material comprises a non-stoichiometric Ti-Ta-Nb-Zr submicron powder, wherein the powder is a nanopowder. See column 4, lines 57-62 and column 23-24, example 8. Yadav defines nanopowder as nanostructured materials wherein the domain size is the powder's grain size with domain size less than 500 nanometer, preferably less than 100

nanometers. See column 9, lines 9-10, column 2, lines 55-52 and column 10, lines 65-67. The domain size disclosed by Yadav therefore is the particle size of the powder as evidence by referring to “nanoparticulate non-stoichiometric”, column 12, lines 51-57, and the disclosure of “the small size of the nanostructured non-stoichiometric substances will make them readily transportable through pores and capillaries”, column 12, lines 22-24.

Yadav teaches (column 24, lines 17-19) the use of non-stoichiometric nanoscale powders is the potential use of non-toxic elements in orthopedic and other medical implant which is the same as having cytocompatibility within interfacing biological cell. Yadav also discloses (column 24, lines 19-22) the biomedical implants are engineered to control properties such as strength, toughness, modulus, corrosion resistance, biocompatibility, porosity, surface roughness, and wear resistance, which the same as exhibiting mechanical functionality with interfacing biological cell.

Yadav does not specifically teach the non-stoichiometric alloy exhibit osteoblast adhesion between the implant and the interfacing biological cell, however the claimed osteoblast adhesion would have been inherently possessed by the medical material of Yadav since it is one of the criteria in material used for forming orthopedic devices.

Regarding claim 13, Yadav does not disclose the claimed surface roughness. However since the roughness is the measurement of the finish or roughness on the surface of the powder, the surface roughness of powder would be less than 500 nanometers as it can't be larger than the size of the powder itself. As for claims 14-15, the titanium alloy powder taught by Yadav would inherently have the claimed surface roughness since it has the same particle size as the

instant claimed biomaterial powder. Therefore, the burden is on the applicant to prove that the product of the prior art does not necessarily or inherently possesses characteristics attributed to the claimed product. In re Spade, 911 F.2d 705,708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and also see MPEP § 2112.01.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yadav in view of Davidson (U.S. Patent No. 5,415,704).

Yadav teach the biomaterial for use in implantable orthopedic devices substantially as claimed. Yadav however does not teach the type of material as recited the instant claims.

Davidson discloses that Ti-6Al-4V and Co-Cr-Mo (F75 or F799) are known for use as biomaterials in orthopedic implantation (column 1, lines 26-29). Note that Co-Cr-Mo (F75 or F799) is the alloy having the claimed composition as disclosed in the specification [0011].

Because both Yadav and Davidson biomaterial for orthopedic implantation, it would have been obvious to one of skilled in the art to replace one biomaterial for the other to in making an implantable orthopedic device since the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Applicant's arguments filed 8/24/09 have been fully considered but they are not persuasive.

The applicant argues that Yadav et al discloses forming metallic orthopedic devices from powders having grain sizes less than 500 nm but devoid of any teaching or suggestion regarding the desired surface roughness or the particle size of the compositions. The examiner agrees that Yadav is silent about the surface roughness but does not agree that Yadav does not teach the particle size. Yadav not only teach the grain size but also teach the particle size as evidence by Yadav defining nanopowder as nanostructured materials wherein the domain size is the powder's grain size and the referring to "nanoparticulate non-stoichiometric", column 12, lines 51-57, and "the small size of the nanostructured non-stoichiometric substances will make them readily transportable through pores and capillaries", column 12, lines 22-24. As discussed in the rejection of claims 14 since the roughness is the measurement of the finish or roughness on the surface of the powder, the surface roughness of Yadav's powder would be less than 500 nanometers as it can't be larger than the size of the powder itself. Furthermore, the titanium alloy powder taught by Yadav would inherently have the claimed surface roughness since it has the same particle size or grain size as the instant claimed biomaterial powder.

Regarding an argument that that similar grain sizes can produce different surface roughness based on the orientation of the grains as noted in publication by Woodcock et al, and that the same grain sizes oriented in a different manner would have different roughness. The argument is noted however it is not persuasive since there is no teaching the in the specification of the orientation of the grain or any structure difference(s) between the powder of Yadav and that of the applicant.

Applicant also argues that an article by Nelson and Deng that clearly demonstrates that those skilled in the art appreciate that grain size (crystal size), particle size and surface

roughness are three separate and distinct physical characteristics of a material and that alteration of any one of these properties can impact the physical properties of the material. This is not persuasive since the article is to a different type of material, i.e., ceramic powder as opposed to alloy powder. Thus the argument is not convincing.

As for the submission of Declaration under CFR 1.132 by Dr. Webster, the examiner does not find any further support since the Declaration is made on a different material that is nanosize polymer instead of nanosize alloy powder.

For the reasons above the rejections of claims 1-11 made in previous office action is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NGOCLAN T. MAI whose telephone number is (571)272-1246. The examiner can normally be reached on 8:30-5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy King/
Supervisory Patent Examiner, Art Unit
1793

n.m.